

Independent Quality Controls for Roche **cobas**® Mass Spectrometry Solution



Independent Third Party Mass Spectrometry Quality Controls for Roche **cobas**® i 601 analytical unit





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A fully integrated sample-to-results solution

Laboratory design, integration and automation have always been central to Roche Diagnostics. Over the years Roche has pioneered the integration of all disciplines into the core lab, and importantly connecting the data.

Today, the healthcare industry is focused on Mass Spectrometry (Mass Spec) to empower clinical laboratory medicine diagnostics, opening new avenues for personalized medicines. The advantages of Mass Spec are clear. Superior sensitivity and specificity.

The Roche cobas® Mass Spec solution now brings fast turnaround, high throughput, full automation, connected to LIS, robust ready-for-use reagents, and fully integrated into the core lab.

Mass Spec is offering labs an unbiased, consistent method to evaluate a vast number of substances, such as sex hormones and therapeutic drugs with typically better specificity and sensitivity compared to traditional immunoassays.





The **cobas**® Mass Spec solution, will be fully integrated into the core lab and **cobas® pro** integrated solutions together with immunoassay and clinical chemistry analyzers and ISE.

Enhance laboratory efficiencies with Technopath independent quality control solutions

Technopath have partnered with Roche to develop the portfolio of load and go quality controls for the cobas® i 601 analytical unit.

Technopath consolidated QC materials deliver labour savings by reducing handling requirements involved in running a QC process. Independent studies have also shown that a reduction in the physical handing of quality control vials can lead to a reduction in transposition errors made by laboratory staff. Consolidated controls lead to a reduction in packaging waste, meaning more environmentally friendly, and in dead volume waste, meaning more economically attractive.

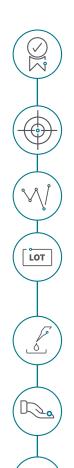
The Technopath software programme, IAMQC°, compliments Multichem Quality Controls by enabling laboratories to compare their QC results with laboratories globally. Automated connectivity streamlines data collection, reducing QC analysis and reporting time.







Technopath and Roche help your laboratory achieve greater efficiencies in QC processes through reduced handling time, reduced costs and barcoded vials.



Accreditation/regulatory compliance

Independent QC material facilitates meeting accreditation and regulatory guidelines, such as CLIA, CLSI, CAP, ISO and RiliBÄK.

Targeted at clinical decision points

Quality controls targeted at clinical decision points, giving clinicians' confidence in the validity of test results.

Value assigned

Value assignment saves technologist time when setting up initial reference intervals.

Automated configuration of new QC lots

Faster turn around time for quality control set up. Use the automated QC configuration process to upload the QC targets and ranges directly on to your Roche system, reducing errors and increasing productivity.

Human-based matrices

Human-based matrices provide patient-like performance with commutability in test measurement to increase confidence in QC results.

Reduction in handling errors

All Technopath Multichem controls are liquid, meaning no reconstitution of lyophilised controls.

Streamlined supply chain

Reduction in the number of part numbers to be purchased streamlines the supply chain. Fewer part numbers equates to a lower number of lots to manage.



Results upload to IAMQC Peer with Roche cobas® mobile solutions connector

Automatic upload of QC results to IAMQC Peer. [1]

Inter-Lab QC comparison reports

Technopath IAMQC® Peer software offers Six-Sigma, Levey-Jennings, Youden, Bias, Group Coordinator, Measurement of Uncertainty, Monthly Summary, and Exceptions reports to give your laboratory the information it requires to monitor QC. Multiple languages are supported. [2] [3]

^{1.} Contact your Roche representative for more information on the cobas Mobile Solutions Connector.

^{2. &}quot;The laboratory shall participate in inter-laboratory comparisons" ISO15189:2022.

^{3. &}quot;[A] laboratory should actively participate in inter-laboratory QC programs when such programs are available." CLSI C-24 4th edition.



Enhance Laboratory Efficiencies with Multichem® Independent Quality Controls and IAMQC® QC data management software.



CONSOLIDATION

Fewer products required to meet your core laboratory control needs, leading to increased operational efficiencies and reduced waste.



AUTOMATION

Load and go barcoded controls with target values and ranges pre-loaded on the cobas enterprise system, reducing handling and setup time.



QUALITY

Independent, 3rd party, humanmatrix based controls with analytes targeted at clinical decision points supporting clinician quality goals.

Internal Laboratory Quality Control (IQC) is important in ensuring confidence in patient test results and in meeting accreditation requirements including CLIA, CLSI, CAP, RiliBÄK and ISO.

Increasingly Laboratories seek objective assessment and comparison of analytical methods and instrumentation performance, to meet their quality goals.

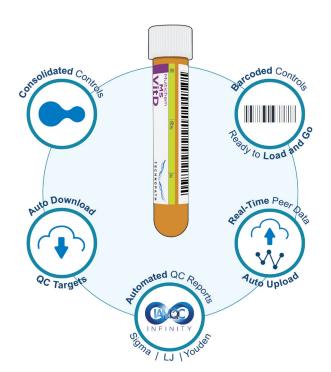
Technopath's Independent quality control solution, Multichem QC and IAMQC software, provides clinical laboratories with significant cost, handling and time savings, whilst delivering higher confidence in analytical testing methods.

Advancing Quality Control in the Clinical Laboratory

By utilising Multichem barcoded QC materials, laboratories can optimise their QC workflow and minimise handling errors. It is supported and complemented with IAMQC® data management system.

Learn more here:

https://www.technopathclinicaldiagnostics. com/knowledge-centre-roche-customer/





A Guide on How to Access and Review Multichem Instructions for Use (IFU)

Multichem independent third party quality control (QC) materials are classed as in-vitro diagnostic medical devices. Therefore, it is important that the Instructions For Use (IFU) for each lot is read and adhered to.

The IFU contains important information in relation to:

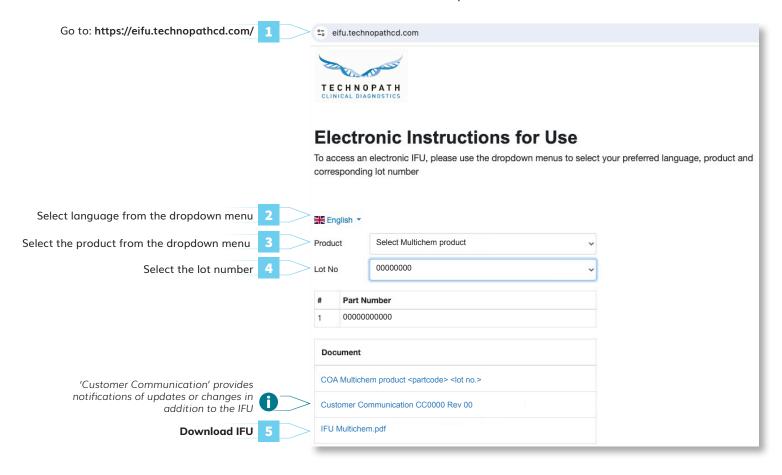
- Precautions that users should take while handling the product
- Procedure for use
- Storage, stability and exceptions where applicable
- Limitations of the product
- Representative values, specific to each lot of product



Accessing Multichem IFUs

https://eifu.technopathcd.com/

Multichem IFUs for Roche cobas® are available from the Technopath eIFU website.





Important information contained in the Multichem IFU

All details contained with the IFU are important . For daily running of QC, particular attention should be given to the sections below.

Precautions

PRECAUTIONS

Warning: Biological source material. Treat as potentially infectious.

For In Vitro Diagnostic Use.

All users should make themselves familiar with the precautions set out in the IFU. This information will help the user to take the necessary steps for the safe handling of materials.

Procedure for Use

PROCEDURE FOR USE

This product should be treated the same as patient specimens and run in accordance with the instructions accompanying the instrument, kit, or reagent

Procedure for use varies between different Multichem controls. Laboratory personnel should review product specific handling information.

Storage

STORAGE

This product will be stable until the expiration date when stored unopened

Multichem control storage requirements vary between products. Multichem quality controls are stable until the expiration date when stored correctly.

Product Stability & Exceptions



Review each lot number for product specific stability claims and exceptions

Limitations

LIMITATIONS

- Do not use the product past the expiration date.
- If there is evidence of microbial contamination or excessive turbidity in the product, discard the tube.

Refer to the material limitations, ensuring correct use of the product.

Representative Values



Analyte target values and ranges are provided in the IFU. Values are derived from multiple replicates and are specific for each lot.

Target values and ranges can be downloaded onto compatible cobas® instruments via Cobas Link.





Multichem® **MS TDMs**

QC to monitor accuracy and precision of laboratory testing procedures for therapeutic drugs



Features

- Human-based proprietary formulation
- Mimics performance of patient samples
- Direct load, liquid, for ease of use
- · Assayed quality control
- Test consolidated
- Barcoded vials for ease of use
- Assayed and value assigned for Roche **cobas**® i 601 analytical unit
- Bi-level utility

Specifications

- 24 months closed vial stability at -20°C to -80°C
- 5 days open vial stability at 2°C to

Product	Description	Configuration	PART NO
Multichem MS TDMs	Assayed Level 1	12 x 4.5mL (54mL)	09922571190
	Assayed Level 2	12 x 4.5mL (54mL)	09922580190

Analytes with performance and stability claims:

Amikacin Carbamazepine Carbamazepine-10,11-epoxide Gabapentin Gentamicin Lamotrigine

Methotrexate Mycophenolic Acid (MPA) Mycophenolic Acid Glucuronide Phenobarbital Phenytoin Primidone **Tobramycin**

Topiramate Valporic Acid Vancomycin Voriconazole Zonisamide

Analytes below may be present in the product. No claims are made regarding performance and stability.

Acetaminophen Digoxin Levetiracetam Meropenem

Linezolid

Piperacillin Salicylate Theophylline





Multichem® **MS Free TDMs**

QC to monitor accuracy and precision of laboratory testing procedures for therapeutic drugs



Features

- Human-based proprietary formulation
- Mimics performance of patient samples
- Liquid, for ease of use
- · Assayed quality control
- Test consolidated
- Assayed and value assigned for Roche **cobas**® i 601 analytical unit
- Bi-level utility

Specifications

- 24 months closed vial stability at -20°C to -80°C
- 10 days open vial stability at 2°C to 8°C

Product	Description	Configuration	PART NO
Multichem MS Free TDMs.	Assayed Level 1	12 x 4.5mL (54mL)	10162066190
	Assayed Level 2	12 x 4.5mL (54mL)	10162074190

Analytes with performance and stability claims:

Phenytoin, free Valproic Acid, free

Analytes below may be present in the product. No claims are made regarding performance and stability.

Phenytoin Valproic Acid





Multichem[®] **MS VitD**

QC to monitor accuracy and precision of laboratory testing procedures for vitamin D



Features

- Human-based proprietary formulation
- Mimics performance of patient samples
- Direct load, liquid, for ease of use
- Assayed quality control
- Test consolidated
- Barcoded vials for ease of use
- Assayed and value assigned for Roche **cobas**® i 601 analytical unit
- Bi-level utility

Specifications

- 24 months closed vial stability at -20°C to -80°C
- 10 days open vial stability at
- 2°C to 8°C

Product	Description	Configuration	PART NO
Multichem MS VitD	Assayed Level 1	12 x 4.5mL (54mL)	09922555190
	Assayed Level 2	12 x 4.5mL (54mL)	09922563190

Analytes with performance and stability claims:

24,25-Dihydroxy Vitamin D2 24,25-Dihydroxy Vitamin D3 24,25-Dihydroxy Vitamin D total

25-Hydroxy Vitamin D2 25-Hydroxy Vitamin D3 25-Hydroxy Vitamin D total

Analytes below may be present in the product. No claims are made regarding performance and stability.

1,25-Dihydroxy Vitamin D2

1,25-Dihydroxy Vitamin D3





Multichem[®] **MS ISDs**

QC to monitor accuracy and precision of laboratory testing procedures for immunosuppressant drugs



Features

- Human-based proprietary formulation
- Mimics performance of patient samples
- Liquid for ease of use
- Assayed quality control
- Test consolidated
- Assayed and value assigned for Roche **cobas®** i 601 analytical unit
- Bi-level utility

Specifications

- 24 months closed vial stability at -20°C to -80°C
- 10 days* open vial stability at 2°C to 8°C

Product	Description	Configuration	PART NO
Multichem MS ISDs	Assayed Level 1	12 x 4.5mL (54mL)	09922598190
	Assayed Level 2	12 x 4.5mL (54mL)	09922601190

Analytes with performance and stability claims:

Cyclosporine Everolimus

Sirolimus **Tacrolimus**



^{* 10} days open vial stability for all analytes with the exception of Everolimus, which has 5 days open vial stability.



Multichem® **MS Steroids**

QC to monitor accuracy and precision of laboratory testing procedures for steroids



Features

- Human-based proprietary formulation
- Mimics performance of patient samples
- Direct load, liquid, for ease of use
- Assayed quality control
- Test consolidated
- Barcoded vials for ease of use
- Assayed and value assigned for Roche **cobas**® i 601 analytical unit
- Bi-level utility

Specifications

- 24 months closed vial stability at -20°C to -80°C
- 5 days open vial stability at 2°C to

Product	Description	Configuration	PART NO
Multichem MS Steroids	Assayed Level 1	12 x 4.5mL (54mL)	09922512190
	Assayed Level 2	12 x 4.5mL (54mL)	09922547190

Analytes with performance and stability claims:

17-Hydroxyprogesterone Aldosterone Androstenedione Cortisol

Cortisone DHEA **DHEA-S** Dihydrotestosterone Estradiol Progesterone Testosterone





IAMQC® Interlaboratory peer program



The easiest way to automate QC data from Technopath's Multichem[®] independent quality controls.

Technopath's **IAMQC** interlaboratory peer program enables a laboratory to choose **real-time peer comparison** from laboratories within group or across the globe for all QC test data. This allows the laboratory to easily monitor its own reliability and precision.



https://register.iamqc.com

- Full automation options available
- Daily comparison of internal lab system or global comparisons
- Powerful automated inter-laboratory QC Comparison Reports
- Track shifts and trends over time and across reagent lots
- **Meet accreditation requirements** for Peer Comparison



Setting up Roche cobas[®] instruments with IAMQC[®] interlaboratory peer program

It's as simple as step 1, 2 and 3.



REGISTER

Fill laboratory details in to the online Activation Form here: https://register.iamqc.com

ACTIVATE

Account is activated by Technopath after verification

LOGON

Once the account is activated, the laboratory will receive login details and a user guide



Mass spectrometry quality controls for Roche cobas® i 601 analytical unit

Order information:

Order through your local Roche affiliate

Product	Features	Specifications	Part Code	Kit Config
Multichem MS TDMs	 Assayed QC Bi-level utility Direct load, liquid, for ease of use Human-based proprietary formulation 	 24 months closed vial stability at -20°C to -80°C 5 days open vial stability at 2°C to 8°C 	Level 1: 09922571190 Level 2: 09922580190	12 x 4.5mL (54mL) 12 x 4.5mL (54mL)
Multichem MS Free TDMs	Assayed QC Bi-level utility Liquid, for ease of use Human-based proprietary formulation	24 months closed vial stability at -20°C to -80°C 10 days open vial stability at 2°C to 8°C	Level 1: 10162066190 Level 2: 10162074190	12 x 4.5mL (54mL) 12 x 4.5mL (54mL)
Multichem MS VitD	Assayed QC Bi-level utility Direct load, liquid, for ease of use Human-based proprietary formulation	24 months closed vial stability at -20°C to -80°C 10 days open vial stability at 2°C to 8°C	Level 1: 09922555190 Level 2: 09922563190	12 x 4.5mL (54mL) 12 x 4.5mL (54mL)
Multichem MS ISDs	Assayed QC Bi-level utility Liquid, for ease of use Mimics performance of patient samples	24 months closed vial stability at -20°C to -80°C 10 days* open vial stability at 2°C to 8°C	Level 1: 09922598190 Level 2: 09922601190	12 x 4.5mL (54mL) 12 x 4.5mL (54mL)
Multichem MS Steroids	Assayed QC Bi-level utility Direct load, liquid, for ease of use Mimics performance of patient samples	24 months closed vial stability at -20°C to -80°C 5 days open vial stability at 2°C to 8°C	Level 1: 09922512190 Level 2: 09922547190	12 x 4.5mL (54mL) 12 x 4.5mL (54mL)

^{* 10} days open vail stability for all analytes with the exception of Everolimus, which has 5 days open vial stability.



Other Multichem quality controls for compatible Roche cobas® systems

Order information:

Order through your local Roche affiliate

Product	Features	Specifications	Part Code	Kit Config
Multichem IA Plus	Assayed Immunoassay QC Tri-level utility Direct load, liquid for ease of use Human-based proprietary formulation	36 month closed vial stability at -20°C to -80°C 10 day open vial stability at 2°C to 8°C	Level 1: 09339825190 Level 2: 09339841190 Level 3: 09339850190	12 x 4mL (48mL) 12 x 4mL (48mL) 12 x 4mL (48mL)
Multichem S Plus	 Assayed Chemistry QC Tri-level utility Direct load, liquid for ease of use Human-based proprietary formulation 	 36 month closed vial stability at -20°C to -80°C 10 day open vial stability at 2°C to 8°C 	Level 1: 09339795190 Level 2: 09339809190 Level 3: 09339817190	12 x 4mL (48mL) 12 x 4mL (48mL) 12 x 4mL (48mL)
Multichem P	 Assayed immunoprotein QC Direct load, liquid for ease of use Human-based proprietary formulation 	36 month closed vial stability at -20°C to -80°C 14 day open vial stability at 2°C to 8°C	Level P: 09339884190	12 x 4mL (48mL)
Multichem U	 Assayed urine chemistry QC Bi-level utility Direct load, liquid for ease of use Mimics performance of patient samples 	 24 month closed vial stability at 2°C to 8°C 30 day open vial stability at 2°C to 8°C 	Level 1: 09339868190 Level 2: 09339876190	12 x 3mL (36mL) 12 x 3mL (36mL)
Multichem ID-G	 Qualitative quality control optimized for Roche cobas® systems and reagents. Direct load, liquid for ease of use Human-based proprietary formulation Mimics performance of patient samples 	 24 month closed vial stability at 2°C to 8°C 30 day open vial stability at 2°C to 8°C 	09339892190	4 x 4mL (16mL)
Multichem ID-HIV p24	 Qualitative quality control optimized for Roche cobas® systems and reagents. Direct load, liquid for ease of use Human-based proprietary formulation Mimics performance of patient samples 	 24 month closed vial stability at 2°C to 8°C 30 day open vial stability at 2°C to 8°C 	09915494190	4 x 4mL (16mL)
Multichem ID-GNeg	 Qualitative quality control optimized for Roche cobas® systems and reagents. Direct load, liquid for ease of use Human-based proprietary formulation Mimics performance of patient samples 	 36 month closed vial stability at 2°C to 8°C 30 day open vial stability at 2°C to 8°C 	09339906190	4 x 4mL (16mL)



Additional complementary independent quality controls from **Technopath Clinical Diagnostics**

Product Name	Technopath List No.	Kit Config.	Analytes	Feature Set
Multichem A1c Single level (level 1) assayed Single level (level 2) assayed Bi-level Assayed	HB001A HB002A HB000A	12 x 1mL 12 x 1mL 2 x 6 x 1mL	• HbA1c	 24 month closed vial stability at -20°C to -80°C 30 day open vial stability at 2°C to 8°C
Multichem AE Single level (level 1) assayed Single level (level 2) assayed Single level (level 3) assayed Bi-level assayed Tri-level assayed	AE611A AE612A AE613A AE600A AE610A	12 x 2mL 12 x 2mL 12 x 2mL 2 x 6 x 2mL 3 x 4 x 2mL	Ammonia Ethanol	 36 month closed vial stability at -20°C to -80°C 14 day open vial stability at 2°C to 8°C
Multichem AMH Single level (level 1) assayed Single level (level 2) assayed Single level (level 3) assayed Tri-level assayed	AM501A AM502A AM503A AM500A	12 x 2mL 12 x 2mL 12 x 2mL 3 x 4 x 2mL	• Anti-Müllerian Hormone	 36 month closed vial stability at -20°C to -80°C 30 day open vial stability at 2°C to 8°C
Multichem CSF Single level (level 1) assayed Single level (level 2) assayed Bi-level assayed	CF101A CF102A CF100A	12 x 2mL 12 x 2mL 2 x 6 x 2mL	• Glucose • Lactate • IgG • Protein	 36 month closed vial stability at -20°C to -80°C 30day open vial stability at 2°C to 8°C
Multichem D-Dimer Single level (level 1) assayed Single level (level 2) assayed Bi-level assayed	DM901A DM902A DM900A	12 x 1mL 12 x 1mL 2 x 6 x 1mL	• D-Dimer	 36 month closed vial stability at -20°C to -80°C 30 day open vial stability at 2°C to 8°C
Multichem hsTn Single level (assayed)	HS301A	12 x 3mL	Troponin I Troponin T	36 month closed vial stability at -20°C to -80°C 10 day open vial stability at 2°C to 8°C
Multichem IA Speciality Single level (level 1) assayed Single level (level 2) assayed Single level (level 3) assayed Tri-level Assayed	BP301A BP302A BP303A BP300A	12 x 2mL 12 x 2mL 12 x 2mL 3 x 4 x 2mL	ACTH BNP Calcitonin Procalcitonin PTH Intact	 36 Month Closed Vial Stability at -20°C to -80°C 7 day open vial stability at 2°C to 8°C
Multichem NB Single level (assayed)	NB800A	12 x 2mL	Direct Bilirubin Total Bilirubin Caffeine* Theophylline	36 month closed vial stability at -20°C to -80°C 14 day open vial stability at 2°C to 8°C
Multichem WBT Tri-level assayed	WB000A	3 x 4 x 2mL	Cyclosporine Red Blood Cell Folate* Glucose* Sirolimus Tacrolimus	30 month closed vial stability at -20°C to -80°C 10 day open vial stability at 2°C to 8°C

^{*}Refer to lot specific IFU for analyte performance and stability claims.



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